

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

MAYNARD et al.

Serial No.: Not yet assigned

Filed: Herewith

For: **OPTICAL ASSAY DEVICE AND
METHOD**

Group Art Unit: Not yet assigned

Examiner: Not yet assigned

PRELIMINARY AMENDMENT

Commissioner for Patents
Washington, D.C. 20231

Sir:

In conjunction with the Divisional Application filed herewith, please enter the following amendments and consider the following remarks.

CERTIFICATE OF MAILING
(37 C.F.R. §1.10)

I hereby certify that this paper (along with any referred to as being attached or enclosed) is being deposited with the United States Postal Service on the date shown below with sufficient postage as 'Express Mail Post Office To Addressee' in an envelope addressed to the Commissioner for Patents, Washington, D.C. 20231.

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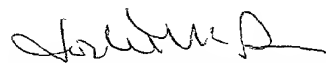
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IN THE CLAIMS

Please cancel all currently pending claims without prejudice to their future prosecution.
Please add the following new claims.

34. (New) A method for detecting the presence or amount of an analyte of interest in a test sample, comprising:

providing an optical assay device, said optical assay device comprising a base comprising absorbent material, and a member comprising an optically active test stack, said member rotatably coupled to said base for rotation between a lowered position where said optically active test stack contacts said absorbent material and a raised position where said optically active test stack does not contact said absorbent material;

applying said test sample to said optically active test stack, wherein said member is in said lowered position;

applying a conjugate to said optically active test stack;

applying a wash to said optically active test stack;

rotating said member to said raised position;

applying an amplifying reagent solution to said optically active test stack;

rotating said member to said lowered position; and

observing said optically active test stack for a visual indication of the presence or amount of the analyte of interest.

35. (New) A method for detecting the presence or amount of an analyte of interest in a test sample, comprising:

providing an optical assay device, said optical assay device comprising a base comprising absorbent material, and a member comprising an optically active test stack, said member rotatably coupled to said base for rotation between a lowered position where said optically active test stack contacts said absorbent material and a raised position where said optically active test stack does not contact said absorbent material;

applying said test sample to said optically active test stack, wherein said member is in said raised position;

rotating said member to said lowered position;
applying a wash to said optically active test stack;
rotating said member to said raised position;
applying an amplifying reagent solution to said optically active test stack;
rotating said member to said lowered position;
applying a wash to said optically active test stack; and
observing said optically active test stack for a visual indication of the presence or
amount of the analyte of interest.

36. (New) The method of claim 34 or 35 further including incubating said optically active
test stack after applying said test sample and after applying said amplifying reagent solution.

REMARKS

The present invention relates to methods and devices for flow-through optical assay for
the detection of an analyte of interest in a sample that conveniently allows control of the flow
characteristics of the sample through the device without significant user intervention.

Claims 1-33 are presently pending in the instant application. Applicants have cancelled
all pending claims herein, and added new claims 34-36. The new claims are commensurate in
scope to claims 31-33, which were cancelled by the Examiner's Amendment as non-elected
claims in the co-pending US Patent Application No. 09/272,641. Thus, the new claims are fully
supported by the specification and do not introduce new matter. For example, the specification
describes a method for detecting an analyte of interest in a test sample *e.g.*, on page 9, lines 3-19;
page 25, line 17 through page 26, line 14.

Notwithstanding the foregoing, Applicants expressly reserve the right to pursue subject
matter no longer or not yet claimed in the instant application in one or more applications which
may claim priority hereto.

CONCLUSION

Applicants respectfully submit that the pending claims are in condition for allowance. An early notice to that effect is earnestly solicited. Should any matters remain outstanding, the Examiner is encouraged to contact the undersigned at the address and telephone number listed below so that they may be resolved without the need for additional action and response thereto.

Date July 11, 2001

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Respectfully submitted,

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